

Message Text

UNCLASSIFIED

PAGE 01 BONN 10341 061617Z
ACTION HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-07 /026 W
-----085528 070139Z /62

R 061556Z JUN 78
FM AMEMBASSY BONN
TO SECSTATE WASHDC 9131

UNCLAS BONN 10341

DEPT PASS FDA

E.O. 11652: N/A
TAGS: OGEN, ETRD, EIND, TBIO, GW
SUBJECT: FDA ADVISORY - DEFECTIVE INTRA-AORTIC BALLOON
PUMPS (RECALL T-098-8)

REF: STATE 138793/1

1. IN ACCORDANCE WITH REFTTEL, EMBASSY BONN CONTACTED
AND ALERTED THE GERMAN CONSIGNEES OF AVCO BALLOON PUMPS
WHO, IN SOME CASES, ALREADY HAD RECEIVED NOTIFICATION
OF A POSSIBLE DEFICIENCY. THE CONSIGNEE HOSPITALS
AND CLINICS PLAN TO CONTACT AVCO'S GERMAN REPRESENTATIVE
WHERE DIFFICULTIES WITH THE PUMP HAVE ARISEN.

2. LATE FDA ADVISORIES OF THIS NATURE HAVE BEEN
RECEIVED LATELY IN AN INCREASING NUMBER. OUR
EXPERIENCE SHOWS THAT IT WOULD BE BETTER IF "WARNINGS"
COULD BE ISSUED BY THE EMBASSY AT THE SAME TIME AS,
OR AT LEAST SHORTLY AFTER THE ORIGINAL RECALL BY THE
U.S. MANUFACTURER. (WE NOTE AVCO'S NOTIFICATION TO
ITS CUSTOMERS WAS ISSUED TWO MONTHS AGO.) INTERVENTION
BY THE EMBASSY AT A LATER DATE TENDS TO CAUSE THE
CONSIGNEES UNCERTAINTY WHETHER CORRECTIVE MEASURES
CARRIED OUT BY THE MANUFACTURER IN THE INTERVAL HAVE
BEEN SUFFICIENT OR WHETHER REINVESTIGATION WILL BE
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REQUIRED. EARLY NOTIFICATION COULD AVOID EMBARRASSMENT
WHERE PROMPT ACTION ALREADY HAS BEEN TAKEN BY THE
MANUFACTURER.

3. IT WOULD ALSO FACILITATE EMBASSY ACTION IF FDA
RECALLS WOULD PROVIDE INFORMATION ON THE U.S. COMPANY'S
REPRESENTATIVES WITHIN THE HOST COUNTRY AS POSSIBLE

CONTACT POINT.
STOESSEL

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NNN

Message Attributes

Automatic Decaptioning: X
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Decaption Date: 01 jan 1960
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Disposition Approved on Date:
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Disposition Comment:
Disposition Date: 01 jan 1960
Disposition Event:
Disposition History: n/a
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Disposition Remarks:
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